June 29, 2000

Via email http://dms.dot.gov
Docket # RSPA-99-6283

Document Management System
U.S. Department of Transportation
400 Seventh Street, S.W.
Washington, D.C. 20590-0001

Re: Advance Notice of Proposed Rulemaking
Compatibility with IAEA ST-1 Regulations
Docket Number RSPA-99-6283

Dear Sir/Madam:

Neutron Products Inc. ships a significant number of Type B packages internationally, and although we philosophically agree that the DOT and IAEA regulations should be compatible and not conflicting, we have potential serious problems with ST-1 as written.

NEUTRON'S QUALIFICATION TO COMMENT

With regard to our experience and qualifications:

- We have been shipping cobalt-60 sources and irradiated targets internationally for about a quarter of a century.

- We have made more than 300 international ocean and air shipments containing about 15 million curies.

- All of our shipments are round-trip, and most are "Radioactive Material, Special Form, N.0.S.," UN2974, Class 7, Schedule 10 for both outbound and return carriages.

- However, the return shipments for about 100 of the ocean and air shipments have been "Radioactive Material, Excepted Package - Empty Packaging," UN 2910, Schedule 7, Class 4.

- In addition, we have made more than 50 shipments of "Radioactive Material, Excepted Package - Articles Manufactured from Depleted Uranium," UN 2910, Schedule 7, Class 3, as part of our exporting cobalt-60 teletherapy units.

All of the above shipments have been made safely and without incident.

Neutron's shipping packages are:

- currently approved by the DOT under the 1973 edition;

- designed and used not only as shipping packages, but also include components which are designed to mount directly to various teletherapy units in order to facilitate the safe transfer of cobalt-60 teletherapy sources (which contain 100's of TBqs) in hospitals and private clinics.

SIGNIFICANT AND CRITICAL

Our current understanding is that if:

- Neutron can demonstrate to the NRC that our 1973 packaging meets the requirements of the 1985 edition (which we believe that we can do) and,

- the DOT accepts the NRC's technical evaluation that our packaging meets the 1985 edition,

then:

- the DOT would be in a position to expeditiously upgrade our 1973 Certificate of Competent Authority to a 1996 Certificate because ST-1 does not change the physical requirements of a Type B shipping package.

However, if the foregoing understanding is flawed, and the effect of the DOT's harmonization with ST-1 (particularly Paragraph 816) is to preclude the continued unrestricted use of our teletherapy shipping/transfer packaging then:

- Neutron Products Inc. would, in all likelihood, be eliminated as a supplier of cobalt-60 teletherapy sources; and,

- what we believe is currently the only viable mechanism for the replacement or removal of cobalt-60 sources which are currently installed in some of the older model teletherapy units at various locations around the world would also be eliminated.

The above statements are based on the following facts.

Paragraph 816 refers to "multilateral approval of package design" which could be interpreted to mean that, in order for Neutron to continue to use its existing shipping packages, it would have to obtain approval from every country through which the shipment passes. Such multilateral approval may be practical when there are repeated shipments between two points. However, since Neutron's Type B teletherapy source shipping/transfer package shipments are from Dickerson, Maryland to hospitals and clinics throughout the world, it would be too time consuming and costly to obtain multilateral approval for each shipment of teletherapy sources.

Traditionally, the shipping packages used by original manufacturers of teletherapy units are designed only for the transfer of sources to their specific units. On the other hand, Neutron's shipping packages are universal, that is to say they can be used to exchange sources in all of the major models of teletherapy units. To the best of our knowledge, Neutron's universal source shipping/transfer packaging are the only ones which are technically suitable for the removal and installation of the sources for all manufacturers and models of teletherapy units, and which are currently approved for international shipments.

Teletherapy units that were manufactured in the 1970's are currently in use for the treatment of cancer patients. Many of the manufacturers of those units (Siemens, Westinghouse, Kelleket-Barnes, etc.) are no longer engaged in the teletherapy business and are, therefore, no longer in a position to recover sources from those units when the hospital wishes to return the source.

No one is going to make the investment necessary to qualify new teletherapy source shipping/transfer packaging to the 1996 edition for removing and installing these older teletherapy units.

Further, the fact that Paragraph 818 limits the currently approved Special Form radioactive material to use before December 31, 2003 will inhibit, and may actually prevent, the return of existing cobalt-60 sources which were shipped under obsoleted Special Form Certificates, and may have been shipped over two decades ago.

Without a practical, economically reasonable, mode of returning existing sources from the older teletherapy units, the probability that they will be "stored" or disposed of in an unsafe manner dramatically increases, which in turn, makes repeating the incidents that have already occurred in Mexico, Brazil, Turkey and Thailand almost inevitable. Certainly, this will not increase the health and safety of the public.

CONCERNS AND RECOMMENDATION

If the net effect of the DOT adopting ST-1 is to increase the cost and difficulty of maintaining cobalt-60 teletherapy shipping/transfer packages to the point that such shipments are impractical, hospitals and physicians will utilize treatments not involving cobalt-60 for the treatment of their cancer patients. Alternative radiation therapy modalities are more expensive and can be less efficacious, depending on the type of cancer.

The broader scope of public benefit, which includes the treatment of cancer patients, justifies the use of the Neutron's well maintained shipping/transfer packages indefinitely.

The overall effect of implementing the requirements of Paragraphs 526, 527, 573, 816, 817 and 818 will result in a significant decrease in the health and safety of the public by:

- **S** significantly increasing the cost of delivered cobalt-60 teletherapy sources;

- encouraging cancer treatment facilities to delay purchases of a new source, which, in sequence, increases the treatment time of cancer patients, increases the amount of healthy tissue exposed to radiation due to patient movement during the treatment; decreases the effectiveness of the treatment and increases the side effects;

- providing an incentive for the replacement of cobalt-60 teletherapy units with linear accelerators, resulting in an increase in medical treatment costs, a decrease in the number of available treatment units, a decrease in the number of patients treated, an increase in the number of adverse reactions for patients with head, neck and breast cancers, and a decrease in the number of patients treated due to the difficulty and cost of traveling to the treatment units.

As described earlier, we believe the adverse implications described in the foregoing discussion to be unintended potential consequences of ST-1, and if DOT's harmonization with ST-1 does not prevent the continued unrestricted use of our shipping packages then the issues presented above obviously would not be applicable. However, if such is not the case, then we believe that significant adverse conditions presented above will result, without any prospective off-setting public benefit of substance.

Our specific comments on ST-1 are as follows:

Paragraphs 526 & 7

There needs to be a provision for not applying the factor which depends on the cross-section of a freight container.

The use of a factor which depends on the cross-section of a freight container to increase the measured TI from a freight container appears to assume that the radioactive material fills the entire freight container. When there is only one approved Type B radioactive package in the freight container, as there are in most of Neutron's shipments, the measured TI should be the actual TI.

Applying the factor under the conditions described in ST-1 would unnecessarily increase the concerns associated with the shipment, and thereby decrease the probability that a carrier would accept the shipment.

Paragraph 562

We applaud the elimination of the requirement for segregation from foodstuffs. The requirement to segregate our shipments from foodstuffs has often been the major reason given for the refusal of containerized ocean carriers to accept our shipments. We look forward to a greater acceptance of our shipments based on this change.

Paragraph 573

In addition to the driver and assistants, individuals whose exposure is monitored under a radiation

protection program should be permitted in road vehicles carrying radioactive material.

Source handlers and their assistants who are involved in the loading and unloading of the radioactive material at the vehicle's destination often ride with the vehicle, especially on trips which are less than a day. Requiring them to travel separately will increase delivery costs and the ordinary risks associated with transportation, without any benefit. We submit that it is important to keep various risks in proportion. In its 33 years of operations in Maryland, while none of Neutron's employees has suffered any radiation injury, two of them have been lost to traffic accidents while traveling to and from work.

Thank you for the opportunity to review and comment on ST-1. We would be pleased to meet with the DOT to explore the detrimental effects of ST-1 on the treatment of cancer patients and what we believe to be viable alternatives.

Regards,

Neutron Products, Inc.

Marvin M. Turkanis
Vice President